

APR 01 2013

**VERTEX® Reconstruction System
510(k) Summary
February 25, 2013**

- I. Company:** Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738
- Contact:** Claire Evans
Senior Regulatory Affairs Specialist
- II. Proprietary Trade Name:** VERTEX® Reconstruction System
- III. Classification Name:** Spinal Interlaminar Fixation Orthosis, 21 CFR 888.3050
- IV. Classification:** Class II
- V. Product Codes:** KWP
- VI. Product Description:** The VERTEX SELECT® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.
- The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. Some components contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel.
- To achieve best results, do not use any of the VERTEX® Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another MEDTRONIC document. As with all orthopaedic and neurosurgical implants,

none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.

- VII. Indications:** When intended as an adjunct to fusion of the occipitocervical spine, cervical spine, and the thoracic spine (Occiput-T3), the VERTEX® Reconstruction System is indicated for skeletally mature patients using allograft and/or autograft for the following:
DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion, and/or tumors.

Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks

The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.

Note: Segmental fixation is recommended for these constructs.

Hooks and Rods

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws

The use of multi-axial screws is limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

Connectors

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX® Reconstruction System to the CD HORIZON® Spinal System screws, hooks, and connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

VIII. Summary of Technological Characteristics: The purpose of this 510(k) is to add additional components to the VERTEX® Reconstruction System. The subject and predicate parts are identical in terms of material, indications for use, intended use, and performance specifications. The key differences between the subject and predicate devices are length and the addition of an angled open connection option.

IX. Identification of Legally Marketed Devices: The design features, materials and indications for use of the subject devices are substantially equivalent to predicate VERTEX® Reconstruction System devices cleared in K083071 (S.E. 11/14/2008) and K121191 (S.E. 06/29/12).

The labeling is identical to that cleared in K121191 (S.E. 06/29/12).

X. Discussion of the Non-Clinical Testing: Medtronic performed compression fatigue, static compression and static torsion on the subject connectors in accordance with ASTM 1717-12.

Non-clinical testing in the form of design verification and validation activities was performed on the subject devices to show equivalence to the previously listed predicate devices.

XI. Conclusions: A risk analysis and non-clinical testing was completed for the changes incorporated into the subject devices. The test results and additional supporting documentation provided in this submission demonstrated substantial equivalence of the subject devices to the predicate devices cleared in K083071 (S.E. 11/14/2008).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
% Ms. Claire Evans
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Letter dated: April 1, 2013

Re: K123906

Trade/Device Name: VERTEX® Reconstruction System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: February 25, 2013
Received: February 26, 2013

Dear Ms. Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123906Device Name: VERTEX® Reconstruction System

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K123906